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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

7 CFR Part 331

9 CFR Part 121

[Docket No. APHIS-2014-0095]

RIN 0579-AE08

Agricultural Bioterrorism Protection Act of 2002; Biennial Review and Republication of the Select Agent and Toxin List

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Advance notice of proposed rulemaking and request for comments.

SUMMARY: In accordance with the Agricultural Bioterrorism Protection Act of 2002, we are soliciting public comment regarding the list of select agents and toxins that have the potential to pose a severe threat to animal or plant health, or to animal or plant products. The Act requires the biennial review and republication of the list of select agents and toxins and the revision of the list as necessary. Accordingly, we are soliciting public comment on the current list of select agents and toxins in our regulations and suggestions regarding any addition or reduction of the animal or plant pathogens currently on the list of select agents.

DATES: We will consider all comments that we receive on or before [Insert date 60 days after date of publication in the Federal Register].

ADDRESSES: You may submit comments by either of the following methods:

- Federal eRulemaking Portal: Go to  
<http://www.regulations.gov/#!docketDetail;D=APHIS-2014-0095>.
- Postal Mail/Commercial Delivery: Send your comment to Docket No. APHIS-2014-0095, Regulatory Analysis and Development, PPD, APHIS, Station 3A-03.8, 4700 River Road Unit 118, Riverdale, MD 20737-1238.

Supporting documents and any comments we receive on this docket may be viewed at <http://www.regulations.gov/#!docketDetail;D=APHIS-2014-0095> or in our reading room, which is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799-7039 before coming.

FOR FURTHER INFORMATION CONTACT: Dr. Charles L. Divan, Unit Director, Agricultural Select Agent Services, APHIS, 4700 River Road Unit 2, Riverdale, MD 20737-1231; (301) 851-3300.

SUPPLEMENTARY INFORMATION:

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 provides for the regulation of certain biological agents and toxins that have the potential to pose a severe threat to human, animal, and plant health, or to animal and plant products. The Animal and Plant Health Inspection Service (APHIS) has the primary responsibility for implementing the provisions of the Act within the U.S. Department of Agriculture (USDA). Veterinary Services (VS) select agents and toxins, listed in 9 CFR 121.3, are those that have been determined to have the potential to pose a severe threat to animal health or animal products. Plant Protection and

Quarantine (PPQ) select agents and toxins, listed in 7 CFR 331.3, are those that have been determined to have the potential to pose a severe threat to plant health or plant products. Overlap select agents and toxins, listed in 9 CFR 121.4, are those that have been determined to pose a severe threat to public health and safety, to animal health, or to animal products. Overlap select agents are subject to regulation by both APHIS and the Centers for Disease Control and Prevention, which has the primary responsibility for implementing the provisions of the Act for the Department of Health and Human Services.

Title II, Subtitle B of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (which is cited as the “Agricultural Bioterrorism Protection Act of 2002” and referred to below as the Act), section 212(a), provides, in part, that the Secretary of Agriculture (the Secretary) must establish by regulation a list of each biological agent and each toxin that the Secretary determines has the potential to pose a severe threat to animal or plant health, or to animal or plant products.

In determining whether to include an agent or toxin in the list, the Act requires that the following criteria be considered:

- The effect of exposure to the agent or toxin on animal or plant health, and on the production and marketability of animal or plant products;
- The pathogenicity of the agent or the toxin and the methods by which the agent or toxin is transferred to animals or plants;
- The availability and effectiveness of pharmacotherapies and prophylaxis to treat and prevent any illness caused by the agent or toxin; and
- Any other criteria that the Secretary considers appropriate to protect animal or plant health, or animal or plant products.

Paragraph (a)(2) of section 212 of the Act requires the Secretary to review and republish the list of select agents and toxins every 2 years and to revise the list as necessary. To fulfill this statutory mandate, PPQ and VS each convene separate interagency working groups in order to review the lists of PPQ and VS select agents and toxins, as well as any overlap select agents and toxins, and develop recommendations regarding possible changes to the list using the four criteria for listing found in the Act. In this document, we are asking for comments on the current list<sup>1</sup> of select agents and toxins and on any other significant pathogens so as to inform the working groups as they begin the biennial review process.

This action has been determined to be not significant for the purposes of Executive Order 12866 and, therefore, has not been reviewed by the Office of Management and Budget.

Authority: 7 U.S.C. 8401; 7 CFR 2.22, 2.80, 371.3, and 371.4.

Done in Washington, DC, this 23<sup>rd</sup> day of February 2015.

Kevin Shea,

Administrator, Animal and Plant Health Inspection Service.

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<sup>1</sup> You may view the lists of select agents and toxins on the Internet at <http://www.selectagents.gov/SelectAgentsandToxinsList.html>.